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K091824

510(k) Summary

Company Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

Contact Glenda Marsh
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Date Prepared October 30, 2009

New Device Name
Trade Name: Ethicon Endo Surgery® Rotating Endoscopic Scissors
Common or Usual Name: Electrosurgical Electrodes
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Product Code GEI)

Predicate Device
Ethicon Endo Surgery® Articulating Hook Knife (K082955)
TeleMed Systems Flexible Endoscopic Scissors (K010412)

Device Description The Ethicon Endo Surgery® (EES) Rotating Endoscopic Scissors are a monopolar electrosurgical instrument intended for cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures. The Rotating Endoscopic Scissors are a sterile, single patient use, disposable instrument consisting of a flexible wire cable and scissors end effector. The end effector can be rotated independently of the shaft. When connected to an electrosurgical generator using a 4.5 mm monopolar cable (not supplied) and activated, the Rotating Scissors delivers a monopolar electrical current to the surgical site. This device passes through gastroscopes having a 2.8 mm or larger working channels. This device is supplied sterile for single-patient use.

Indications for Use The Rotating Endoscopic Scissors are a monopolar electrosurgical instrument intended for cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures.

Technological Characteristics The EES Rotating Endoscopic Scissors device is very similar to the TeleMed Systems Flexible Endoscopic Scissors (K010412) in that it consists of an elongated flexible shaft with scissors end-effectors. Both devices are designed for cutting tissue. The main technological difference between these two devices is that the TeleMed scissors cannot be energized while the new EES Rotating Endoscopic Scissors can deliver RF energy when connected to a Monopolar RF energy supply.

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The EES Rotating Endoscopic Scissors device is also similar to Ethicon Endo Surgery® Articulating Hook Knife (K082955). In both devices, the metal electrode tip is used to deliver monopolar energy to the surgical site. Both devices are designed to be connected to electrosurgical generators, and utilize RF monopolar energy for operation. The main difference between these two devices is the shape of the electrode. In the Articulating Hook Knife, the electrode is in the shape of an "L" hook, while in the new Endoscopic Scissors, the scissors also comprise the electrode. Both devices feature rotation of the electrode. The Rotating Endoscopic Scissors does not contain the articulating feature present in the Articulating Hook Knife.

In all three devices, the handle allows for the manipulation of the electrode via the control knobs.

Performance Data. Bench testing was performed to demonstrate that the EES device performs as intended. The patient contact portions of the device have been evaluated for biocompatibility and comply with the requirements of ISO 10993-1. The device was tested to demonstrate compliance with the following standards:

- Medical Electrical Equipment – IEC 60601 Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- Medical Electrical Equipment - Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment, IEC 60601-2-2, 2006/07/01
- Medical Electrical Equipment - Part 2-18: Particular Requirements for the Safety of Endoscopic Equipment, IEC 60601-2-18, 1996/08/01
- Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility, IEC 60601-1-2 (2004)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Ethicon Endo-Surgery, Inc.
% Ms. Glenda Marsh
QS/RA Project Manager
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K091824
Trade Name: Ethicon Endo-Surgery Rotating Endoscopic Scissors, Model IN2507
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulation Class: Class II
Product Code: GEI
Dated: October 30, 2009
Received: November 2, 2009

Dear Ms. Marsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

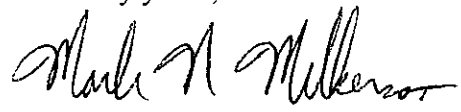
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Ethicon Endo Surgery® Rotating Endoscopic Scissors**

Indications for Use:

The Rotating Endoscopic Scissors are a monopolar electrosurgical instrument intended for cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures.

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091824

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)